

REMARKS

This Amendment is filed in response to the Final Rejection dated December 4, 2002. All objections and rejections are respectfully traversed. Examiner states that claims 1, 2, 4-8, 10, 11, 19, 22, 26, 35-38, 43, 45-49, 56, 79-85, 91-94, and 97 are currently pending in the Application. Applicants herein cancel claims 11, 19, 38, and 43. Applicants herein amend claims 1, 2, 4, 7, 22, 35, 45, 49, 79, and 81. Applicants herein add claim 98. Thus Applicants state that remaining claims 1, 2, 4-8, 10, 22, 26, 35-37, 45-49, 56, 79-85, 91-94, and 97-98 are still pending in the application. Applicants have cancelled and amended claims specifically to put the remaining claims in condition for allowance. No new matter has been added.

At paragraph 1 of the Official Action, Examiner states that the proposed drawing correction is disapproved. However in a subsequent phone conversation on January 17, 2003, Examiner states that reference numbers 341, 350, and 321 are adequately illustrated in FIGs. 1 and 2B, and are therefore not new matter. Applicants understand that the objection of paragraph 1 has been withdrawn.

At paragraph 2 of the Official Action, Examiner has accepted the substitute specification.

At paragraph 3 of the Official Action, Examiner has objected to the amendment of 8/28/02 under 35 USC § 132 because Examiner states that the amendment contains new matter. Applicants have amended claims 7 and 45 according to Examiner's requirements.

At paragraphs 4-5, Examiner states that claims 7, 45, and 81 are rejected under 35 USC § 112, first paragraph, a containing subject matter that was not discussed in the specification. Applicants have amended claims 7, 45 and 81 according to Examiner's requirements.

At paragraphs 6-8, Examiner states the claim 35 is rejected under 35 USC § 112, second paragraph, as failing to particularly point out and distinctly claim the invention. Applicants have amended claim 35 according to Examiner's requirements.

At paragraph 9, Examiner states that claim 19 is rejected under 35 USC § 101 because there exists a positive recitation of a human and/or human anatomy as part of the claimed invention. Applicant herein cancels claim 19.

At paragraphs 10-16, Examiner states that claims 1, 2, 4-8, 11, 26, 35-38, and 43 are rejected under 35 USC § 102(e) as being anticipated by Holland et al., United States Patent # 5,957,904, issued 9/28/1999 (Holland). Applicants do not believe that the female collection device of Holland anticipates Applicants' invention. Applicants herein recite critical differences between Holland and the present invention as claimed.

At paragraphs 17-25, Examiner states that claims 1, 45, 56, 79, 82-85, 91-94, and 97 are rejected under 35 USC § 103(a) as being unpatentable over Anderson, United States Patent # 6,068,618, issued 5/30/2000, in view of Holland. Applicants do not believe that Anderson in view of Holland render Applicants' invention obvious, the reasons for which are spelled out herein.

At paragraph 26, Examiner restates that the amendment of 8/28/02 is objected to under 35 USC § 132. See above.

At paragraph 27, Examiner states that added claim 95 is relabeled to claim 97.

At paragraph 28, Examiner states that claim 22, if rewritten in independent form including all the limitations of the base claim and any intervening claims, is allowable. Applicants have rewritten claim 22 in allowable form and have added claim 98 which is the previous version of claim 22.

At paragraphs 29-30, Examiner states that Applicants' arguments with respect to the election of species have been fully considered but are not persuasive. Applicants herein resubmit the arguments for claims 41 and 87-89 in light of the phone conversation of January 17, 2003 (described previously).

At paragraph 31, Examiner states that the arguments of the previous amendment are moot in view of new grounds for rejection.

Election of species claims

Claim 41: Examiner states that the straps connected to the means for storage are not shown in FIGs. 1, 2A, and 2B. Applicants respectfully point out that the attachment straps 321 are shown but not labeled in FIG. 2B. Applicants have submitted substitute drawing FIG. 2B for Examiner's approval showing the reference numeral 321 identifying Applicants' attachment straps. Applicants respectfully request Examiner's reconsideration of the withdrawal of claim 41.

Claim 87: Examiner states that the absorbent material in the means for storage is drawn to a non-elected species. In substitute drawing FIG. 1, Applicants have labeled absorption/storage elements 350. These elements are described throughout the specification as being constructed of absorbent material. Applicants respectfully request Examiner's reconsideration of the withdrawal of claim 87.

Claim 88: Examiner states that the means for distributing urine is drawn to a non-elected species. In substitute drawing FIG. 1, Applicants have labeled wicking conduits 341. These elements are described throughout the specification as being used to distribute urine throughout the storage container. Applicants respectfully request Examiner's reconsideration of the withdrawal of claim 88.

Claim 89: Examiner states that the means for attaching the storage container is drawn to a non-elected species. In substitute drawing FIG. 2B, Applicants have labeled attachment straps 321. These elements are described throughout the specification as being used to attach the storage container to the leg of the human male. Applicants respectfully request Examiner's reconsideration of the withdrawal of claim 89.

35 U.S.C. § 102 and 103 rejections

The present invention, as set forth in representative claim 1, comprises in part:

1. (Twice Amended) A system for collecting, conveying, and storing urine discharged from a penis of a human male comprising:
 - means for collection of said urine from said human male comprising proximal and distal ends and outer and inner surfaces;
 - means for storage of said urine in an immobilized form before disposal of said urine comprising proximal and distal ends and outer and inner surfaces;
 - means for conveying said urine from said means for collection of said urine to said means for storage of said urine comprising proximal and distal ends and outer and inner surfaces; and
 - means for wicking said urine through a continuous wicking pathway away from the penis wherein said means for wicking moves counter-gravitationally and gravitationally said urine away from the penis through said means for collection and said means for conveying, and deposits said urine in said means for storage.

Unlike Applicants claimed "*A system for collecting, conveying, and storing urine discharged from a penis of a human male*", Holland discloses a *collector* for a human *female* that is not shown to be designed or used by a male (col. 7 lines 59-60). In

contrast, Applicants claim a “*means for collection of said urine from said human male*”, as well as a “*means for storage*”, a “*means for conveying*”, and a “*means for wicking*”, which form a system that is fundamentally different from the collector of Holland.

The collector of Holland contains a wick that runs from the collector through a wicking tube which ends with a conventional fitting. The device drains by gravity into a collection bag (31) which is not further described by Holland. There is no wicking disclosed or suggested between the collector of Holland and the collection bag. There is no means for conveying that sets up a wicking pathway between the collector of Holland and the collection bag.

Holland discloses a side view of the collection device (Holland Fig. 2), and the device in use on its side (Holland Fig. 6). Holland further explains that “[B]y having the wick 30 end at a position...a gravity effect is achieved...and urine ...drains from the reservoir 29 along the wick 30 into...” (col. 4, lines 32-41), and that “[I]n another form of the device, the wick 30 is positioned substantially along the bottom edge 17 of the receptacle 11 so that a gravity effect of urine in the reservoir...”, (col. 4, lines 37-40), and that “[W]ithin the receptacle there is a cone-shaped reservoir which has a wicking system which drains through an orifice into a tubing...” (col. 1, lines 60-62). When the device is in the sideways orientation, Holland anticipates that the flow of urine in the wick is induced by gravity to move through the device and to drain into a container, which itself is outside of the inventive scope of Holland.

Applicants claim “*a system*” that includes not only a *means for collection*, but also a “*means for conveying*” and a “*means for storage*”, integrated by a “*means for wicking*”. Applicants achieve wicking continuity between discreet components by detachable wicking connectors. The benefit of the enhanced transport mechanism, i.e. the delivery emitted urine to a storage device location at an elevation higher than that of the collector, uphill and then downhill fluid transfer, functioning under zero-gravity conditions, is entirely unanticipated by Holland.

Holland’s disclosure of urine flow along a path in a horizontal plane (Holland Fig. 2) actually demonstrates the phenomenon of a gravity-driven spreading flow confined, in

this case, by the wick boundaries. This is analogous to the spreading flow observed when a liquid is poured onto a horizontal flat surface, but is clearly not counter-gravitational. Applicants, on the other hand, claim to enable the flow of urine “*counter-gravitationally*”, a term used herein according to its normal meaning as defined by the *Merriam-Webster Dictionary*: “acting in opposite direction to the force of gravity”. Applicants’ claimed “*means for wicking moves counter-gravitationally and gravitationally*” also makes use of the term wicking according to its normal meaning, for example when a wick draws oil or melted wax up into a flame gravitationally or counter-gravitationally. The capillary action of wicking can cause fluid to be transferred counter-gravitationally, as from a low point of emission to a high point of storage, or from an intermediate elevation of emission over a high point in the transit path to a storage point at a low elevation. The capillary action can even cause fluid to be transferred in the absence of gravity, as in spacecraft above the reach of Earth’s gravity. Holland clearly does not disclose, nor anticipate any capability such as Applicants’ claimed “*moves counter-gravitationally and gravitationally said urine away*”.

Nor does Holland disclose Applicants’ “*means for storage of said urine in an immobilized form*”. Holland’s means for storage, shown as reference number 31 (Holland Figs. 6 and 10), is a collection bag. According to Holland, “the wick 30 is positioned substantially along the bottom edge 17 of the receptacle 11 so that a *gravity effect of urine* in the reservoir also works on the wick to cause urine to be absorbed by the wick 30 prior to draining into the collection bag 31” (col. 4, lines 38-42). Having a “*means for storage of said urine in an immobilized form*” that is maintained as a part of a “*means for wicking . . . through said means for collection and said means for conveying, and deposits said urine in said means for storage*” extending from the interior of the collector to the interior of the storage means enables Applicants’ invention to be capable of inducing urine flow in either counter-gravitational or gravitational directions, or in a sequence of those directions, from point of collection to point of immobilized urine storage. In contrast, Holland discloses only two functions: collection and conveyance. The additional benefits of storing urine in an immobilized form and of providing a wicking pathway to connect to that immobilized storage means are entirely unanticipated by Holland.

Further, Holland discloses only a single piece of wicking material as opposed to connecting discreet wicking pieces by wicking connection means. Holland's description of wicking materials is focused solely on capillary action of a single wicking element within the structure of the collector and the possible extension of that wick into the tube. Holland discloses that the end of such a wick can be somewhere in the middle of the tube or maximally at the end of the tube. Holland clearly states that "the wick 30 may extend for all or part of the length of the tubing 24. The tubing 24 is sealed ...and the tubing 24 has a removable cap at the end. The end can also be connected to a ...bag or bottle 31" (col. 4, lines 26-31). Holland discloses no intention to extend the wick into anything beyond the collector tubing 24. Furthermore, Holland intends that "having the wick 30 end at the position lower than the reservoir 29, a gravity effect is achieved and urine, from a void, drains from the reservoir 29 along the wick 30 into the collection drain or bag 31" (col. 4, lines 32-37). Holland does not anticipate the utility of having the collector and conveyance tube and adsorbent materials in the storage device in wicking connection with one another nor does Holland provide any means for facilitating such wicking continuity. In sharp contrast, Applicants claim a "*means for wicking said urine through a continuous wicking pathway away from the penis wherein said means for wicking moves counter-gravitationally and gravitationally said urine away from the penis through said means for collection and said means for conveying, and deposits said urine in said means for storage*" -- a system that is based upon establishing and maintaining wicking continuity among a plurality of discreet wicking components that are placed in contiguous, removable contact, which contact permits the periodic replacement of individual components when desired. Contiguous contact enables the establishment of "liquid bridging" between the wicking components as a means to transfer the urine between the physically discreet pieces of wicking material.

With respect to wicking material, Holland discloses that the strong hydrophilicity of cotton and viscose rayon are undesirable for Holland's wicking process, and that hydrophobic fibers are to be preferred (col. 5, lines 1-30). Further, Holland discloses a preference of using treated hydrophobic fibers to provide the wicking transfer in Holland's female urinary pouch (col. 5, lines 31-41).

In view of the absence from any cited patent of Applicants' claimed "*means for wicking said urine through a continuous wicking pathway away from the penis wherein said means for wicking moves counter-gravitationally and gravitationally said urine away from the penis through said means for collection and said means for conveying, and deposits said urine in said means for storage*", Applicants respectfully urge that the Holland patent is legally insufficient to render the presently claimed invention anticipated under 35 U.S.C. § 102.

Anderson discloses a male catheter that does not involve wicking. Anderson discloses a design of a urine collection and storage system for human males that features a specific configuration of a male external catheter: one that is constructed of a tubular sheath formed from a single layer of elastic material. The thickness of the sheath varies, being thicker at the proximal end when fitted over the penis, so that the thicker region is able to provide a uniform, radially-compressive force on the penis. Anderson assumed that gravity would drive the flow of urine from collector to storage bag, and did not teach nor suggest the use of a wicking means to move emitted urine from the collection device to storage.

The combination of Holland and Anderson, not taught nor suggested by either invention, only conceptually formulated through impermissible hindsight, falls short of the performance Applicants' integrated "*means for collection . . . means for storage . . . means for conveying . . . and means for wicking said urine through a continuous wicking pathway . . . wherein said means for wicking moves counter-gravitationally and gravitationally said urine away from the penis through said means for collection and said means for conveying, and deposits said urine in said means for storage*".

Holland's use of gravity-driven flow in the wick in his collector is limited to a single piece wick extending from somewhere in the collector to a point somewhere in the conveying tube. Holland does not anticipate the advantage of having adequate wicking in a male collector to enable wicking continuity into the interior content of the storage device as a means to overcome the urine transport limitations imposed by gravity.

What are missing from the combination of Anderson and Holland, but are clearly claimed by Applicants', are the ability of wicking capability to induce urine to flow away from the penis in counter-gravitational direction, thereby enabling passage of urine over points that are higher than the source (*"means for wicking said urine through a continuous wicking pathway away from the penis wherein said means for wicking moves counter-gravitationally and gravitationally said urine away from the penis through said means for collection and said means for conveying, and deposits said urine in said means for storage"*), and the immobilization of the urine in the storage device, which enables more convenient storage and disposal, and also which also enables urine to be wicked to and stored at locations that are higher than the source (*"means for storage of said urine in an immobilized form before disposal of said urine comprising proximal and distal ends and outer and inner surfaces"*).

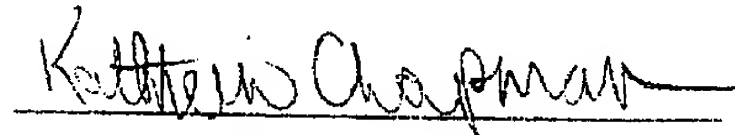
With respect to Anderson's radial compression tube (30), Anderson clearly describes only a single layer sheath in which the compression band is a physical extension of the collecting tube itself. Applicants claim (claim 8) *"means for collection comprises means for wicking the urine away from the penis; thin-wall hollow conduction tube having proximal and distal ends and a cavity sufficiently large to surround the penis; and compression tube having proximal and distal ends and sufficient size to be disposed around and provide radial compression contact upon the penis at said proximal end of said conduction tube, wherein said means for wicking is disposed within said conduction tube."*

In view of the absence from any cited patent of Applicant's claimed *"means for wicking said urine through a continuous wicking pathway away from the penis wherein said means for wicking moves counter-gravitationally and gravitationally said urine away from the penis through said means for collection and said means for conveying, and deposits said urine in said means for storage"*, Applicants respectfully urge that neither Anderson nor Holland, singly or in combination, is legally insufficient to render the presently claimed invention obvious under 35 U.S.C. § 103.

All independent claims are believed to be in condition for allowance. All dependent claims are believed to depend upon allowable independent claims, and therefore in condition for allowance.

Favorable action is respectfully solicited.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Kathleen Chapman", written over a horizontal line.

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**MARK-UP PAGES FOR THE FEBRUARY 4, 2003, AMENDMENT
TO U.S. PATENT APPLICATION SER. NO. 09/606,721**

The replacement for claims 1, 2, 4, 7, 22, 35, 45, 49, 79, 81, and 98 resulted from the following changes:

1. (Twice Amended) A system for collecting, conveying, and storing urine discharged from a penis of a human male comprising:

means for collection of said urine from said human male comprising proximal and distal ends and outer and inner surfaces;

means for storage of said urine in an immobilized form before disposal of said urine comprising proximal and distal ends and outer and inner surfaces;

means for conveying said urine from said means for collection of said urine to said means for storage of said urine comprising proximal and distal ends and outer and inner surfaces; and

means for wicking said urine through a continuous wicking pathway away from the penis wherein said means for wicking moves counter-gravitationally and gravitationally said urine away from the penis through said means for collection and said means for conveying, and deposits said urine in said means for storage.

2. (Twice Amended) The system as in claim 1 further comprising:

first means for connection which connects said means for collection and said means for conveying and which comprises an outer surface and an inner surface, said means for wicking being adjacent to said inner surface of said first means for connection.

wherein said first means for connection enables wicking connection between said means for collection and said means for conveying; and

second means for connection which connects said means for conveying and said means for storage and which comprises an outer surface and an inner surface, said means for wicking said urine being adjacent to said inner surface of said second means for connection, wherein said second means for connection enables wicking connection between said means for conveying and said means for storage,

wherein said first means for connection is selected from a group consisting of fixed and removable, and said second means for connection is selected from a group consisting of fixed and removable, and wherein said distal end of said means for collection is connected to said proximal end of said means for conveying through said first means for connection, and said distal end of said means for conveying is connected to said proximal end of said storage device through said second means for connection, wherein said first means for connection and said second means for connection enable formation of said continuous wicking pathway.

4. (Twice Amended) The system as in claim 1 wherein said means for wicking comprises:

first wicking spacer disposed within said means for collection;

second wicking spacer disposed within said means for conveying;

third wicking spacer disposed within said means for storage of said urine;

[first wicking spacer piece forming] contiguous wicking connections formed

between said first wicking spacer and said second wicking spacer; and

[second wicking spacer piece forming] contiguous wicking connections formed between said second wicking spacer and said third wicking spacer,

wherein said first wicking spacer, said first wicking spacer piece, said second wicking spacer, said second wicking spacer piece, and said third wicking spacer collectively form a complete wicking path from said means for collection to said means for storage.

7. (Twice Amended) The system as in claim 1 wherein said means for wicking comprises a material selected from a group consisting of single component fibers selected from a group consisting of wool, cotton [cellulose], rayon, nylon, and polyester; blended fibers selected from a group consisting of wool, cotton [cellulose], rayon, nylon, and polyester; said single component fibers and said blended fibers being fabricated into a form selected from a group consisting of yarns, woven fabrics, mats, and felts; open-cell foamed polymers selected from a group consisting of polyurethane foams, [polyvinylalcohol foams, and cellulose sponges]; open-mesh fibrous mats of metallic materials selected from a group consisting of steel wool and copper wools; open-mesh fibrous mats of synthetic polymers selected from a group consisting of polypropylene [and nylon]; sheets of flexible solid materials selected from a group consisting of [latex and] polyolefins; films of flexible solid materials selected from a group consisting of latex [and polyolefins].

22. (Twice Amended) [The system as in claim 4] A system for collecting, conveying, and storing urine discharged from a penis of a human male comprising

means for collection of said urine from said human male comprising proximal and distal ends and outer and inner surfaces;

means for storage of said urine before disposal of said urine comprising proximal and distal ends and outer and inner surfaces;

means for conveying said urine from said means for collection of said urine to said means for storage of said urine comprising proximal and distal ends and outer and inner surfaces;

means for wicking said urine away from the penis wherein said means for wicking moves said urine counter-gravitationally and gravitationally away from the penis through said means for collection and said means for conveying, and deposits said urine in said means for storage;

first means for connection which connects said means for collection and said means for conveying and which comprises an outer surface and an inner surface, said means for wicking being adjacent to said inner surface of said first means for connection;
and

second means for connection which connects said means for conveying and said means for storage and which comprises an outer surface and an inner surface, said means for wicking said urine being adjacent to said inner surface of said second means for connection,

wherein said means for wicking comprises first wicking spacer disposed within said means for collection; second wicking spacer disposed within said means for conveying, third wicking spacer disposed within said means for storage of said urine,

wherein said first means for connection enables wicking connection between said means for collection and said means for conveying,

wherein said second means for connection enables wicking connection between said means for conveying and said means for storage,

wherein said first wicking spacer, said first means for connection, said second wicking spacer, said second means for connection, and said third wicking spacer collectively form a complete wicking path from said means for collection to said means for storage, said first wicking spacer comprises a y-shape having a tail and two legs such that said legs of said y-shape lie in proximity to said inner surface of said means for collection.

35. (Twice Amended) The system as in claim 1 wherein said means for conveyance comprises:

waterproof conveyance tube film layer;

conveyance tube having an exterior surface upon which said waterproof conveyance tube film layer is disposed and a hollow interior [into which the penis is placed];

means for wicking said urine through said conveyance tube wherein said means for wicking prevents said interior of said conveyance tube from becoming blocked when crimped or kinked;

wherein said means for wicking is disposed within said conveyance tube film layer and the combination of said means for wicking with said film layer is sufficiently flexible to conform to normal bodily movement and position, and wherein said means for

wicking moves urine by wicking flow from said collection means into said storage means for immobilization.

45. (Twice Amended) A urine collection device for collecting urine from the penis of a human male comprising:

thin-wall hollow conduction tube having proximal and distal ends and a cavity sufficiently large to surround the penis;

compression tube having proximal and distal ends and sufficient radial size at said proximal end to be disposed around and provide radial compression contact upon the penis and said proximal end of said conduction tube; and

means for wicking said urine counter-gravitationally and gravitationally away from the penis [after said urine emerges from the penis] to immobilized storage in a spatially separate device [and while said urine is within said conduction tube and said compression tube], wherein said means for wicking is disposed within [said compression tube and] said conduction tube.

49. (Twice Amended) The urine collection device as in claim 45 wherein said means for wicking comprises a material selected from a group consisting of rayon acetate needled felting; single component fibers selected from a group consisting of wool, cotton [cellulose], rayon, nylon, and polyester; blended fibers selected from a group consisting of wool, cotton [cellulose], rayon, nylon, and polyester; said single component fibers and said blended fibers fabricated into a form selected from a group consisting of yarns, woven fabrics, mats, and felts; open-cell foamed polymers, elastomers, polyurethane

foams; open-mesh materials, steel wool; meshes of synthetic polymers, polypropylene; flexible solids, and latex.

79. (Twice Amended) A conveyance tube for conveying urine from a human male collection device to a urine storage device comprising:

conduction tube having walls of any thickness and an interior cavity within said walls; and

wicking spacer disposed within said conduction tube wherein said wicking spacer wicks said urine away counter-gravitationally and gravitationally from said human male collection device to a spatially separated storage means, [and] said wicking spacer prevent[s]ing said conveyance tube from completely collapsing when said interior cavity is empty.

81. (Twice Amended) The conveyance tube as in claim 79 wherein said wicking spacer comprises a material selected from a group consisting of aggregation-stabilized aggregates of fibrous materials, said aggregation-stabilized aggregates selected from a group consisting of yarns, woven fabrics, mats, and felts, said fibrous materials selected from a group consisting of single component fibers selected from a group consisting of wool, cotton [cellulose], rayon, nylon, and polyester, and blended fibers selected from a group consisting of wool, cotton [cellulose], rayon, nylon, and polyester; aqueous fluid-wettable, polymer network-stabilized open-cell foamed polymers, selected from a group consisting of polyurethane foams[, polyvinylalcohol foams, and cellulose sponges]; fiber strength-stabilized open-mesh materials selected from a group consisting of wools made

from metals selected from a group consisting of copper and steel, and synthetic polymer meshes made from synthetic polymers selected from a group consisting of polypropylene [and nylon]; and pieces of flexible solids selected from a group consisting of latex rubbers, silicone rubbers, polyethylene films, and polypropylene films.

98. (New) The system as in claim 1 wherein said first wicking spacer comprises a y-shape having a tail and two legs such that said legs of said y-shape lie in proximity to said inner surface of said means for collection.